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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-------------------------|---------------------|------------------|
| 09/772,790      | 01/30/2001  | Endre Markovits Schersl | 22106965.104181     | 2203             |

51738 7590 12/06/2006

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/772,790

Applicant(s)

SCHERSL, ENDRE MARKOVITS

Examiner

Abigail M. Cotton

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 83-94 is/are pending in the application.
- 4a) Of the above claim(s) 87-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to the amendment and remarks submitted on October 24, 2006. Claims 83-94 are pending in the application, with claims 87-94 being withdrawn as drawn to a non-elected invention. Accordingly, claims 83-86 are being examined on the merits herein.

The rejections of the claims as set forth in the office action mailed on July 27, 2006, have been rendered moot by Applicant's cancellation of the previously pending claims.

The rejections as set forth below have been required by Applicant's presentation of new claims 83-68.

### ***Election/Restrictions***

The Examiner notes that newly presented claims 87-94 correspond to previously presented inventive Group II, which was drawn to a method of reducing serum cholesterol levels with the esters of polycosanols. A restriction requirement requiring election between this Group and co-pending Groups I and III-IV was mailed on July 16, 2002, Applicants provisionally elected the claims of Group I in the response submitted on May 13, 2003, and the restriction requirement was made final on June 18, 2003.

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Accordingly, as claims 87-94 correspond to a non-elected invention, these claims are being withdrawn from consideration.

### ***Claim Objections***

Claim 83 is objected to because the word "margarine" has been spelled incorrectly as "mararine". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 84 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite, because it is not clear what is meant by the recitation "the acid moiety of the ester," as recited in the claims. Claims 83 and 85, from which claims 84 and 86 depend, recite "an ester of tetracosanol" and "an ester of docosanol," and thus recite two different ester compounds. Accordingly, claims 84 and 86 are indefinite, because it is not clear which of the esters is being referred to. Are claims 84 and 86 intended to further limit the acid moiety of the ester of tetracosanol, the ester of docosanol, or both? Appropriate correction and/or clarification is required.

In the interests of compact prosecution and for the purposes of applying prior art, claims 84 and 86 are being interpreted to mean that either one of the ester of tetracosanol or the ester of docosanol has an acid moiety that is a carboxylic acid containing from 2 to 22 carbon atoms.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 83-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 910 955 A2 to Hebpurn et al. published April 28, 1999, in view of U.S. Patent No.3,031,376 to Levin et al, issued April 24, 1962.

Hebpurn et al. teaches blends of wax-esters with beneficial health properties that can comprise wax-esters derived from linear alcohols and linear carboxylic acids, either of them having at least 8 carbon atoms (see abstract, in particular.) Hebpurn et al. teaches that preferred acid residues are long chain polyunsaturated fatty acids such as arachidonic acid, EPA or DHA, and also teaches that acids such as oleic acid and/or linoleic acid can be used (see paragraph 0005, in particular.) Hebpurn et al. teaches

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that the long chain alcohol can contain at least 18 carbon atoms (see paragraph 0005-0007, in particular.)

Hebpurn et al. exemplifies a composition comprising behenyl linoleate/oleate made by reacting behenyl alcohol (docosanol) with fatty acids from the hydrolysis of sunflower oil (oleic and linoleic acids) (see paragraphs 0021-0023.) Accordingly, Hebpurn et al. teaches a composition having an ester of linoleic acid with docosanol, and thus teaches a composition having an ester of docosanol as recited in claims 83 and 85. As linoleic acid is a C18 acid, the composition of Hebpurn et al. also meets the limitation of having an ester of a carboxylic acid with 4 to 22 atoms of carbon with docosanol, and thus also meets the carboxylic acid ester limitations of claims 84 and 86. Accordingly, it is considered that Hebpurn et al. teaches a composition containing esters of long chain fatty alcohols such as docosanol, including C<sub>2</sub>-C<sub>22</sub> fatty acid esters thereof.

Hebpurn et al. further teaches that the wax esters of the invention can be used as a fat replacement, and can be used in combination with triglycerides such as vegetable triglycerides and oils (see paragraph 0010, in particular.) Hebpurn et al. teaches that examples of foods into which the wax esters can be incorporated include ice creams, mayonnaise, spreads, and others (see paragraph 0013, in particular.) Thus, Hebpurn et al. teaches that the wax esters in general can be incorporated into food products such as those recited in claim 83.

Hebourn et al. also teaches that the wax esters can be blended with various vegetable triglycerides, such as oils, cocoa butter, etc. (see paragraph 0010, in particular), and thus teaches providing the wax esters with a pharmaceutically acceptable excipient, as recited in claim 85.

Hebourn et al. does not specifically teach a wax ester that is an ester of the specific alcohol tetracosanol (a C<sub>24</sub> alcohol), as recited in claims 83 and 85. However, it is noted that, as discussed above, Hebourn et al. teaches that desirable long chain fatty alcohols for the wax esters are those having at least 18 carbon atoms (see paragraph 0006, in particular), and exemplifies the use of behenyl alcohol (i.e. docosanol, a C<sub>22</sub> alcohol.)

Levin et al. teaches that tetracosanol can be suitably provided in nutritional compositions (see column 1, lines 10-20, in particular.) Levin et al. teaches that tetracosanol in the alcohol form as well as esters of tetracosanol can be suitably administered for beneficial nutritional effects, and can be provided in the form of foods or pharmaceutical preparations (see column 3, line 50 through column 4, line 25, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the tetracosanol of Levin et

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al. as the alcohol moiety in the wax esters of Hebburn et al, because Hebburn et al. teaches that the wax esters are suitable for food products and are desirably formed from long chain fatty alcohols having at least 18 carbon atoms, whereas Levin et al. teaches that tetracosanol (a C24 alcohol) is suitable for use in food and pharmaceutical products in both the alcohol and ester forms, and provides nutritional benefits. Thus, one of ordinary skill in the art would have been motivated to provide tetracosanol as the alcohol moiety in the wax esters of Hebburn et al, with the expectation of providing an alcohol that meets the criterion of having at least 18 carbon atoms and that is also safe for use in food and pharmaceutical preparations. Thus, the teachings of Hebburn et al. and Levy et al. are considered to render obvious food substances and/or compositions with pharmaceutically acceptable components having esters of tetracosanol and docosanol, as recited in claims 83 and 85.

It is furthermore noted that as the teachings of Hebburn et al. and Levy et al. render it obvious to provide the compositions having wax esters of tetracosanol and docosanol, it would furthermore have been obvious to one of ordinary skill in the art to combine the two wax esters into a single food or pharmaceutically acceptable composition, as recited in the claims. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been



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individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Claims 83-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over by WO 98/56883 to Maria Teresa Tacconi, published December 17, 1998, in view of U.S. Patent No.3,031,376 to Levin et al, issued April 24, 1962.

Tacconi teaches that wax esters enriched with omega-3 unsaturated fatty acids can be used as drug and food additives (see abstract, in particular.) Tacconi teaches that the esters are formed from acids such as eicosapentaenoic acid and docosahexaenoic acid (see page 1, lines 21-28, in particular.) Tacconi teaches that the wax esters are prepared by reacting fatty acid esters with a methyl or ethyl alcohol moiety in a transesterification process with an alcohol (see column 3, lines 24-31, in particular), where the alcohol can comprise from 12 to 40 carbon atoms (see page 4, lines 1-10, in particular.)

Tacconi exemplifies forming such a wax ester by a transesterification of a fish oil ester having EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) with behenyl alcohol (docosanol) (see Example 1, page 11, in particular.) Accordingly, Tacconi teaches a composition having an ester of eicosapentaenoic acid and docosahexaenoic acid with docosanol, and thus teaches providing an ester of docosanol, as recited in claims 83 and 85. As eicosapentaenoic acid and docosahexaenoic acid are C4-C22 acids, the composition of Tacconi also meets the

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limitation of having an ester of a carboxylic acid with 4 to 22 atoms of carbon with docosanol, as recited in claims 84 and 86.

Tacconi also teach that the wax esters can be incorporated as drug and food additives for pharmaceutical and dietetic-alimentary purposes (see abstract, in particular.) Thus, Tacconi teaches that the wax esters can be provided with food substances and pharmaceutically acceptable components, as recited in claims 83 and 85.

Tacconi does not specifically teach that the wax esters include an ester of tetracosanol (a C24 alcohol), as recited in claims 83 and 85, although Tacconi does teach that the alcohol moiety of the wax ester can comprise from 12 to 40 carbon atoms, and exemplifies wax esters of docosanol (a C22 alcohol.) Tacconi also does not specifically teach providing the wax esters with one of the food substances as recited in claim 83.

Levin et al. teaches that tetracosanol can be suitably provided in nutritional compositions (see column 1, lines 10-20, in particular.) Levin et al. teaches that tetracosanol in the alcohol form as well as esters of tetracosanol can be suitably administered for beneficial nutritional effects, and can be provided in the form of foods or pharmaceutical preparations (see column 3, line 50 through column 4, line 25, in particular.)

Levin also teaches that suitable food and pharmaceutical carriers for such nutritional components can include vegetable oils (see column 4, lines 25-40), and thus teaches providing the food substances and pharmaceutically acceptable excipients as recited in claim 83 and 85.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the tetraconanol of Levin et al. as the alcohol moiety in the wax esters of Tacconi, because Tacconi teaches that the wax esters are suitable for food and drug products and are desirably formed from long chain fatty alcohols having 12 to 40 carbon atoms, whereas Levin et al. teaches that tetracosanol (a C<sub>24</sub> alcohol) is suitable for use in food and pharmaceutical products in both the alcohol and ester forms, and provides nutritional benefits. Thus, one of ordinary skill in the art would have been motivated to provide tetracosanol as the alcohol moiety in the wax esters of Tacconi, with the expectation of providing an alcohol that meets the criterion of having from 12 to 40 carbon atoms and that is also safe for use in food and pharmaceutical preparations. Thus, the teachings of Tacconi and Levin et al. are considered to render obvious food substances and/or compositions with pharmaceutically acceptable components having esters of tetracosanol and docosanol, as recited in claims 83 and 85.

It would furthermore have been obvious to provide the vegetable oil of Levin et al. as the food substance/pharmaceutically acceptable excipient in the composition of Tacconi, because Tacconi teaches that the compositions can be used for food and drugs, whereas Levin et al. teaches that vegetable oils are suitable carriers for food and pharmaceuticals. Thus, one of ordinary skill in the art would have been motivated to provide the vegetable oils with the expectation of providing a suitable carrier for food and/or drug compositions.

It is furthermore noted that as the teachings of Tacconi and Levy et al. render it obvious to provide the compositions having wax esters of tetracosanol and docosanol, it would furthermore have been obvious to one of ordinary skill in the art to combine the two wax esters into a single food or pharmaceutically acceptable composition, as recited in the claims. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

### ***Response to Arguments***

Applicant's arguments with respect to the rejections of the claims have been considered but are moot in view of the new grounds of rejection.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

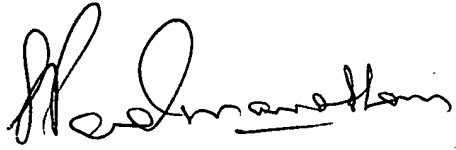
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



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SUPERVISORY PATENT EXAMINER